

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF TEXAS
NORTHERN DIVISION

LORI CAVANAUGH, ET AL
INDIVIDUALLY & ON BEHALF OF
ALL OTHERS SIMILARLY SITUATED

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VS.

C.A. NO. 3:12 cv 4200

NEW ENGLAND COMPOUNDING
PHARMACY, INC., D/B/A NEW ENGLAND
COMPOUNDING CENTER

JURY DEMANDED

PLAINTIFFS' FOURTH AMENDED ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiffs, Lori Cavanaugh ("Cavanaugh"), Helene Shafer ("Shafer"); Sandra Davis Harbor ("Harbor"); Donald Rorie ("Rorie"); Barbara Raphael ("Raphael"); Earl Frye ("Frye"); Perry Friday ("Friday"); and Patrick Bingman ("Bingman"), Individually and on behalf of all others similarly situated (collectively referred to as "Plaintiffs"), complaining of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), Defendant, and for cause of action would show until this Honorable Court as follows:

Parties

1. Plaintiff, Lori Cavanaugh, is a resident of the state of Michigan.
2. Plaintiff, Helene Shafer, is a resident of the State of Indiana.
3. Plaintiff, Sandra Davis Harbor, is a resident of the State of Texas.
4. Plaintiff, Donald Rorie, is a resident of the State of Texas.
5. Plaintiff, Barbara Raphael, is a resident of the State of Michigan.
6. Plaintiff, Earl Frye, is a resident of the State of Florida.

7. Plaintiff, Perry Friday, is a resident of the State of Alabama.

8. Plaintiff, Patrick Bingman, is a resident of the State of Michigan.

9. Defendant, New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, is a foreign corporation registered to do business in the State of Texas, doing business in the state of Michigan and in the State of Texas, as well as various other states in the United States. NECC may be served with citation by serving its registered agent, C.T. Corporation System, at 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201-4234.

Summary

10. Plaintiffs received epidural injections of a steroid to ease their chronic back pain.

11. The steroid, methylprednisolone acetate, was manufactured by Defendant NECC.

12. Unknown to Plaintiffs, or medical staff administering the injections, a fungus contaminated the steroid, rendering the material dangerous and unfit for use. NECC produced and sold more than 17,000 single-dose vials of the steroid, which are believed to be contaminated. At least 131 or more injections have been performed in Dallas, Dallas County, Texas, including the injection given to Plaintiffs Harbor and Rorie.

13. This case seeks redress for NECC's sale of the defective and dangerously contaminated steroid, which has caused Plaintiffs and others bodily harm, emotional distress, other personal injuries, and to incur medical and other expenses.

14. NECC voluntarily recalled the steroid, along with scores of other medicines, after the Center for Disease Control and Prevention ("CDC") confirmed an outbreak of fungal meningitis in people who received injections of the steroid.

15. According to the CDC, "fungal meningitis occurs when the protective membranes that cover the brain and spinal cord are infected with a fungus. Fungal

meningitis can develop after a fungus spreads through the bloodstream from somewhere else in the body, as a result of the fungus being introduced directly into the central nervous system, or by direct extension from an infected body site next to the central nervous system."

16. As of the filing of this complaint, the CDC was aware of and had confirmed 247 instances in which a person developed fungal meningitis after receiving a steroid injection produced by NECC. This outbreak is present in fifteen (15) states, including Texas. At least nineteen people have died as a result of developing fungal meningitis through an injection of the steroid sold by NECC, according to the CDC.

Plaintiffs

17. Plaintiff Cavanaugh is a resident of White Pigeon, Michigan. Plaintiff Shafer is a resident of Granger, Indiana. Plaintiff Harbor is a resident of Arlington, Texas. Plaintiff Rorie is a resident of West, Texas. Plaintiff Raphael is a resident of Suttons Bay, Michigan. Plaintiff Frye is a resident of Pensacola, Florida. Plaintiff Friday is a resident of Jemison, Alabama. Plaintiff Bingman is a resident of Charlevoix, Michigan. In addition, many of the class members are residents of Texas. At all relevant times, Plaintiffs have resided and are citizens as stated above.

Defendant

18. NECC is in the business of manufacturing, marketing and selling medicines. Among the products that NECC manufactures, markets and sells is methylprednisolone acetate, an injectable steroid.

19. NECC is a Massachusetts corporation that maintains its principal place of business at 697 Waverly Street in Framingham, Massachusetts.

Jurisdiction and Venue

20. This Court has jurisdiction over the parties. The damages suffered by Plaintiffs exceed \$75,000 and more than 130 injections have been performed in this District of the State of Texas, including the injection(s) received by Plaintiffs Harbor and Rorie. This Court has jurisdiction over the parties, the putative class, and the causes of action asserted herein pursuant to Rule 23 of the Federal Rules of Civil Procedure and under the Class Action Fairness Act, 28 U.S.C. §1332(d), as the amount in controversy exceeds \$5 million.

21. Venue in this forum is proper because Plaintiffs Harbor and many other victims/class members reside and/or received treatment in Dallas County, Texas, and the causes of action for Plaintiffs and many class members arose, in part, in Texas.

22. NECC conducts business within Texas, delivers product to Texas, and purposefully directs sales and marketing efforts to Texas and its residents.

Factual Background

NECC's production of contaminated steroid

23. NECC is a compounding pharmacy, which means NECC creates custom-mix solutions, creams, and other medications in does or forms that generally are not commercially available.

24. Compounding pharmacies, such as NECC, are exempt from strict FDA oversight, since they are only supposed to prepare individual prescriptions unavailable through regular avenues, such as those with a unique dosage. Further, the products they create are not subject to approval by the Food and Drug Administration ("FDA").

25. NECC manufactured the injectable steroid at its Massachusetts facility, and it sold several hundred single dose vials of the subject methylprednisolone acetate steroid doses in Texas.

26. NECC violated Massachusetts state regulations that forbids such pharmacies from mass-producing drugs.

27. In early October, 2012, FDA investigators located fungal contamination in a sealed vial of the steroid at NECC's facilities. The discovery prompted NECC to recall 17,676 single-dose vials of the steroid.

Widespread Impact

28. Even though NECC recalled the steroid in early October, thousands of people at outpatient clinics and similar facilities in 23 states, including Texas, were injected with the steroid in 2012.

29. The CDC has confirmed 247 cases in which people developed fungal meningitis after receiving the contaminated steroid. At least nineteen people have died as a result of receiving the contaminated steroid. The incubation period for fungal meningitis is anywhere between a few days to one month, so health officials believe the number of victims will increase.

30. According to the CDC, people who develop fungal meningitis may have symptoms that include: headache, fever, nausea and stiffness of the neck. Infected people may also feel confused, dizzy, or discomfort from bright lights.

31. Some of the people who have received the contaminated steroid have suffered strokes as a result of the tainted injection.

Texas Impact

32. According to the Dallas County Health and Human Services, at last two clinics/hospitals in a Texas clinic, Dallas Back Pain Management, potentially administrated the contaminated steroid. In addition, Tarrant County officials report more than 100 patients received the injection at Texas Health Harris Methodist Hospital in Southlake, Texas. Plaintiff Harbor received her injection at Arlington Medical Center in Arlington, Dallas County, Texas. Plaintiff Rorie received his injection at Hillcrest Hospital in Waco, Texas.

Facts Specific to Class Representatives, Lori Cavanaugh, Helene Shafer, Sandra Davis Harbor, Donald Rorie, Barbara Raphael, Earl Frye, Perry Friday and Patrick Bingman

33. After receiving the injections, Plaintiffs suffered headaches, nausea, dizziness, stiffness in their neck, malaise, chills and fever, anxiety and emotional distress since receiving the injection and said symptoms continue.

34. Plaintiffs underwent medical testing, including medical blood work and laboratories, multiple spinal taps, and other analyses as a result of being injected with NECC's defective and contaminated steroid and is waiting on results.

35. Plaintiffs have suffered personal injuries, emotional distress, and have incurred medical and other expenses as a direct result of being exposed to NECC's defective and contaminated steroid and not knowing if they will survive, and will incur medical and other expenses into the future.

Class Action Allegations

36. Pursuant to FED. R. CIV. P. 23, Plaintiffs bring this action for themselves and on behalf of a class ("the Class") defined as:

All natural persons domiciled or residing in any of the fifty states of the United States of America or in the District of Columbia, who received an injection of methylprednisolone acetate steroid dose that was contaminated by a fungus, that was manufactured by NECC,

from June 1, 2012 to the present, and incurred costs related to and purchase of the defective product.

37. Plaintiffs specifically excludes NECC and its related entities, all subsidiaries and affiliates of NECC, any entity in which NECC has a controlling interest, and any and all of NECC's employees, affiliates, legal representatives, heirs, successors or assignees.

38. Plaintiffs also exclude from the putative class any person or entity that has previously commenced and concluded a lawsuit against NECC arising out of the subject matter of this lawsuit.

39. Plaintiffs also specifically exclude from the putative class the judge assigned to this case and any member of the judge's immediately family.

40. Plaintiffs and her counsel reserve the right to modify or amend the class definition, if appropriate, as this class proceeds.

FED. R. CIV. P. 23(a) Prerequisites

41. This class action satisfies numerosity, commonality, typicality, adequacy and superiority requirements for maintaining a class.

42. Certification of the Plaintiffs' claims for class-wide treatment is appropriate because Plaintiffs can prove the elements of their claims and can disprove NECC's defenses, using common, class-wide evidence.

43. **Numerosity.** The class is so numerous that joinder of all members is impracticable. At this time, Plaintiffs do not know the exact size of the Class. Based on information and belief, the Class is comprised of thousands of members who were injected with the contaminated steroid, methylprednisolone acetate, in at least 23 states, and is so geographically dispersed as to render joinder of all Class members impracticable and not feasible.

44. **Ascertainability.** Membership in the putative class is easily ascertained through the records of medical facilities, outpatient clinics, and similar facilities at which people received injections of the contaminated steroid, methylprednisolone acetate.

45. NECC's recall of the contaminated steroid, methylprednisolone acetate, establishes that identifying putative class members will be easily accomplished through its records and the prescribing records of the administering medical professionals.

46. **Commonality.** Pursuant to Rule 23(a)(2) of the Federal Rules of Civil Procedure, the claims of Plaintiff and the putative Class involve common questions of fact and law, that predominate any individualized issues. The evidence in this case will provide answers to questions that are common to members of the class. Those questions, for which common evidence will provide answers, include, but are not limited to the following:

47. Were NECC's methylprednisolone acetate steroid does defectively designed for their intended application, and if so, what is the nature of the defect?

48. Were NECC's methylprednisolone acetate steroid doses defectively manufactured for their intended application, and if so, what is the nature of the manufacturing defect?

49. Did NECC exercise reasonable care in the design, manufacture, and testing of the methylprednisolone acetate steroid doses?

50. Were NECC's methylprednisolone acetate steroid doses unreasonably dangerous for their expected and intended use?

51. Did NECC fail to warn about the dangers associated with its methylprednisolone acetate steroid doses?

52. Did NECC violate the state regulations in Massachusetts where the methylprednisolone acetate steroid doses were manufactured?

53. Did NECC negligently warn or fail to warn Plaintiffs of defects in the methylprednisolone acetate steroid doses that Defendant either knew or should have known existed?

54. Did NECC mass produce vials of the methylprednisolone acetate steroid doses?

55. Did NECC negligently test or fail to test the subject methylprednisolone acetate steroid doses?

56. Did NECC negligently inspect or fail to inspect the subject methylprednisolone acetate steroid doses?

57. Did NECC breach the implied warranty of fitness for particular purpose with regard to the subject methylprednisolone acetate steroid doses?

58. **Typicality.** Plaintiffs' claims are typical of the putative Class Members' claims. As described above, Defendant NECC's wrongful acts and misconducted caused the Plaintiffs and all members of the putative class who were injected with the subject methylprednisolone acetate steroid doses to suffer damages.

59. **Adequacy.** Plaintiffs will fairly and adequately protect the interests of the putative Class. Plaintiffs are members of the subject Class. Plaintiffs' interests coincide with, and are not antagonistic to, other Class Members' interests. Additionally, Plaintiffs have retained counsel experienced and competent in complex, commercial, multi-party, mass tort, consumer, and class action litigation. Plaintiffs' counsel has prosecuted complex class actions in state and federal courts across the country.

FED. R. CIV. P. 23(a) Prerequisites

60. **Superiority.** Questions of law and fact common to the Class predominate over questions affecting only individual Members, and a class action is superior to other available

methods for fair and efficient adjudication of the controversy. A class action in this instance conserves the resources of the putative class, NECC, and the Court. On information and belief, no Attorney General of any state has brought an enforcement action against NECC to remedy the claims asserted herein. Serial adjudications in numerous venues are not efficient, timely or proper. Judicial resources throughout the United States will be unnecessarily depleted by resolution of individual claims. Individualized judgments and rulings could result in inconsistent relief for similarly situated plaintiffs. Individualized lawsuits could also establish incompatible standards of conduct for NECC in creating, marketing, sale and post-sale conduct in connection with its products. Thus the question of individual damages will not predominate over legal and factual questions common to the class.

Count I – Strict Liability

61. Plaintiffs re-allege the foregoing paragraphs, inclusive, as though fully set forth herein.

62. Upon information and belief, NECC is the exclusive designer and manufacturer of the contaminated methylprednisolone acetate steroid doses and is solely responsible for its introduction to the market.

63. The contaminated methylprednisolone acetate steroid doses reached Plaintiffs without a substantial change in the condition in which they were manufactured and intended for use.

64. NECC had a duty to use reasonable care in designing and manufacturing the methylprednisolone acetate steroid doses such that they are not unreasonably dangerous to users when used as directed or in a way foreseeable to NECC.

65. NECC breached that duty by designing and manufacturing the methylprednisolone acetate steroid doses in a defective condition unreasonably dangerous to the Plaintiffs.

66. The methylprednisolone acetate was defective because (1) the substance diverged from its intended design and was tainted with fungal matter that harmed Plaintiffs; and (2) the design and manufacturing did not satisfy normal consumer expectations.

67. If the methylprednisolone acetate steroid doses had been properly designed and manufactured, Plaintiffs would not have been harmed.

68. As a direct and proximate result of NECC's breach of its duty to use reasonable care in the design and manufacture of methylprednisolone acetate, Plaintiffs have suffered serious bodily harm, other personal injuries and emotion distress, and has incurred medical and other expenses.

69. NECC is strictly liable to the Plaintiffs for its defective design and manufacture of methylprednisolone acetate in an amount to be proven at trial.

Count II – Breach of Contract/Warranty

70. Defendant NECC breached its contract/warranty in selling a defective product that was not suitable for human use as well as breaching state regulations in Massachusetts.

Count III - Negligence

71. Plaintiffs reallege the foregoing paragraphs, inclusive, as though fully set forth herein.

72. NECC was negligent because it failed to use reasonable care when it designed, tested, manufactured, marketed and sold doses of methylprednisolone acetate.

73. As the designer, tester, manufacturer and/or seller of consumer products, NECC owed a duty to Plaintiffs to provide a safe and quality product. NECC breached those duties.

74. As a direct and proximate result of NECC's negligence, lack of care, and other wrongful acts, Plaintiffs sustained and will sustain damages.

75. As a result of NECC's negligence, Plaintiffs have suffered serious bodily harm, other personal injuries and emotional distress, and have incurred medical and other expenses as a direct cause of being injected with contaminated doses of methylprednisolone acetate.

76. As a direct, proximate and foreseeable result of NECC's negligence, Plaintiffs have been damaged in an amount to be determined at trial.

Count IV - Gross Negligence

77. Defendant's acts or omissions described above, when viewed from the standpoint of Defendants at the time of the act or omission, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiffs and others similarly situated. Defendant had actual, subjective awareness of the risk involved in the above described acts or omissions, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiffs and others.

78. Based on the facts stated herein, Plaintiffs request that exemplary damages be awarded to them from Defendant.

Prayer

79. WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray for relief against NECC as follows:

- a. Certification of this matter as a class action and appointing Plaintiffs and her counsel to represent the class;
- b. Compensation for damages suffered by Plaintiffs;

- c. Award of reasonable attorneys' fees and costs and disbursements incurred herein;
- d. Award of additional damages, remedies and penalties available by law;
- e. Declaring the rights and obligations of the parties as prayed for; and
- f. Such other and further relief the Court deems just and equitable.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing has been furnished to all counsel of record listed below by e-mail; facsimile; overnight delivery; Regular Mail and/or Certified Mail, Return Receipt Requested on December 19, 2012.

/s/ Mitchell A. Toups
Mitchell A. Toups